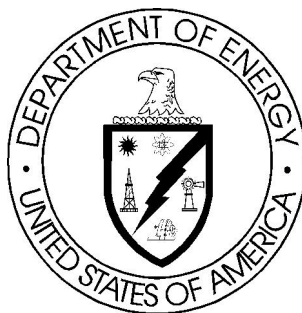


Guidance for the Review of TWRs Privatization Contractor Safety Requirements Document Submittal Package



June 1997

Office of Radiological, Nuclear, and Process
Safety Regulation for TWRs Privatization Contractors

Richland Operations Office
PO Box 550
Richland, WA 99352

PREFACE

The Department of Energy's (DOE) Richland Operations Office (RL) issued the *TWRS Privatization Request for Proposal (RFP)* for Hanford Tank Waste Remediation System (TWRS) Privatization in February 1996. Offerors were requested to submit proposals for the initial processing of the tank waste at Hanford. Some of this radioactive waste has been stored in large underground storage tanks at the Hanford Site since 1944. Currently, approximately 56 million gallons of waste containing approximately 240,000 metric tons of processed chemicals and 250 mega-curies of radionuclides are being stored in 177 tanks. These caustic wastes are in the form of liquids, slurries, saltcakes, and sludges. The wastes stored in the tanks are defined as high-level radioactive waste (10 CFR Part 50, Appendix F) and hazardous waste (Resource Conservation and Recovery Act).

Under the privatization concept, DOE will purchase waste treatment services from a contractor-owned, contractor-operated facility under a fixed-price contract. DOE will provide the waste feedstock to be processed but maintain ownership of the waste. The contractor must: a) provide private financing; b) design the equipment and facility; c) apply for and receive required permits and licenses; d) construct the facility and bring it on-line; e) operate the facility to treat the waste according to DOE specifications; and f) deactivate the facility.

The TWRS Privatization Program is divided into two phases, Phase I and Phase II. Phase I is a proof-of-concept/commercial demonstration-scale effort the objectives of which are to a) demonstrate the technical and business viability of using privatized contractors to treat Hanford tank waste; b) define and maintain adequate levels of radiological, nuclear, process, and occupational safety; c) maintain environmental protection and compliance; and d) substantially reduce life-cycle costs and time required to treat the tank waste. The Phase I effort consists of two parts: Part A and Part B.

Part A consists of a twenty-month development period to establish appropriate and necessary technical, operational, regulatory, business, and financial elements. This will include identification by the TWRS Privatization Contractors and approval by DOE of appropriate safety standards, formulation by the Contractors and approval by DOE of integrated safety management plans, and preparation by the Contractors and evaluation by DOE of initial safety assessments. Of the twenty-month period, sixteen months will be used by the Contractors to develop the Part-A products and four months will be used by DOE to develop views, for input into DOE's Part B Contractor selections, of the Contractors' ability to implement integrated safety management and evaluate Contractor products developed under integrated safety management.

Part B consists of a demonstration period to provide tank waste treatment services by one or more of the TWRS Privatization Contractors who successfully complete Part A. Demonstration will address a range of wastes representative of those in the Hanford tanks. Part B will be 10 to 14 years in duration. Within Part B, wastes will be processed during a 5- to 9-year period and will result in treatment of 6 to 13 percent of the Hanford tank waste.

Phase II will be a full-scale production phase in which the remaining tank waste will be processed on a schedule that will accomplish removal from all single-shelled tanks by the year 2018. The objectives of Phase II are to a) implement the lessons learned from Phase I; and b) process all tank waste into forms suitable for final disposal.

A key element of the TWRS Privatization Contracts is DOE regulation of radiological, nuclear, and integrated safety through the establishment of a specifically chartered, dedicated Regulatory Unit (RU) at RL. This regulation by the RU is authorized by the document entitled *Policy for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors* (referred to as the Policy) and implemented through the document entitled *Memorandum of Agreement for The Execution of Radiological, Nuclear, and*

Process Safety Regulation of The TWRS Privatization Contractors (referred to as the MOA). The Policy is signed by the Under Secretary of Energy; the Manager, DOE Richland Office (RL); the Assistant Secretary for Environment, Safety and Health (ASEH); and the Assistant Secretary for Environmental Management (ASEM). The MOA is signed by the Manager, RL; the ASEH; and the ASEM. The nature and characteristics of this regulation are also specified in these documents. The MOA details certain interactions among RL, the ASEH, and the ASEM as well as their respective roles and responsibilities for implementation of the DOE regulating program.

The authority of the RU to regulate the TWRS Privatization Contractors is derived from the terms of the TWRS Privatization Contracts. Its authority to regulate the Contractors on behalf of DOE is derived from the Policy. The nature and scope of this special regulation (in the sense that it is based on terms of a contract rather than formal regulations) is delineated in the MOA, the TWRS Privatization Contracts, and the four documents from the MOA (listed below), which are incorporated into the Contracts. This special regulation by the RU in no way replaces any legally established external regulatory authority to regulate in accordance with their duly promulgated regulations nor relieves the Contractors from any obligations to comply with such regulations or to be subject to the enforcement practices of the regulatory authority.

The Policy, the MOA, the TWRS Privatization Contracts, and the four documents incorporated in the Contracts define the essential elements of the regulatory program, which will be executed by the RU and to which the TWRS Privatization Contractors must conform. The four documents from the MOA incorporated in the Contracts are:

Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors (Regulatory Concept), DOE/RL-96-0005,

DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors (Regulatory Process), DOE/RL-96-0003,

Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors (To-Level Standards), DOE/RL-96-0006, and

Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization (Standards Identification Process), DOE/RL-96-0004.

In the execution of the regulatory program, the RU will consider not only the approaches and practices of DOE but also the regulatory principles and concepts of the Nuclear Regulatory Commission (NRC). The Policy states that

"It is DOE's policy that TWRS privatized contractor activities be regulated in a manner that assures adequate radiological, nuclear, and process safety by application of regulatory concepts and principles consistent with those of the Nuclear Regulatory Commission."

To this end, the RU will interact with the NRC (under the provisions of a memorandum of understanding with the NRC) during development of regulatory guidance and during execution of the regulatory program to ensure implementation of this policy.

All documents issued by the Office of Radiological, Nuclear, and Process Safety Regulation for TWRS Privatization Contractors are available to the public through the DOE/RL Public Reading Room at the Washington State University, Tri-Cities Campus, 100 Sprout Road, Room 130 West, Richland, Washington.

TABLE OF CONTENTS

1.	Introduction	1
2.	Purpose	1
3.	Attributes	1
4.	SRD Approval Basis - SRD Approval Criteria	1
5.	SRD Review Approach	2
6.	SRD Acceptability Review	5
6.1	Standards	5
6.2	Process and Facility Description	5
6.3	Hazards Assessment	6
6.4	Hazards Control Strategies	6
6.5	Identification Process	7
6.6	Rationale and Justification	7
6.7	Confirmation Process	8
6.8	Standards and Principles	8
6.9	Approval Process	8
6.10	Certification	9
7.	Standards Identification Process Review - Seven Essential Steps	9
7.1	Process Initiation	10
7.2	Identification of the Work	12
7.3	Hazards Evaluation	13
7.4	Identification of Standards	14
7.5	Confirmation Process	16
7.6	Formal Documentation	18
7.7	Certification	20
8.	Technical Review of Hazards Control	21
8.1	Process Element Description	22
8.2	Hazards Assessment	23
8.3	Hazards Control Strategies	25
8.4	Hazards Control Standards	28
8.5	Integration	29
9.	Review of Conformance to Top-level Safety Standards and Principles	32
9.1	Review of Radiological and Nuclear Safety Standards	32
9.2	Review of Radiological and Nuclear Safety Objectives	35
9.3	Review of General Radiological and Nuclear Safety Principles	36
9.4	General Process Safety Principles	37
10.	Review of Compliance to Laws and Regulations	37
11.	Review of Standards Set Justification	39
11.1	Standards Set Justification	39
11.2	SRD Approval or Disapproval	42
12.	Abbreviations	42
13.	Glossary	43
	ENDNOTES	47

LIST OF FIGURES

Figure 5-1. Overall review flow	3
Figure 5-2. Contractor's Process Steps to Develop Recommended Set of Standards	4
Figure 8-1. Integrated Technical Review of Standards	21

LIST OF TABLES

Table 7-1. Process Initiation	11
Table 7-2. Identification of Work	13
Table 7-3. Hazards Evaluation	14
Table 7-4. Identification of Standards	15
Table 7-5. Confirmation of Standards	17
Table 7-6. Formal Documentation	19
Table 7-7. Recommendation by Contractor Representative(Certification)	20
Table 9-1. Dose Standards Above Normal Background	33

1. Introduction

Under Contract, each TWRS Privatization Contractor is required to submit a Standards Approval Package (SAP). An element of the SAP is the Safety Requirements Document (SRD). The U.S. Department of Energy (DOE) Office of Radiological, Nuclear, and Process Safety Regulation for TWRS Privatization Contractors (Regulatory Unit [RU]) at the Richland Operations Office (RL) will evaluate the SRD and issue an Evaluation Report with recommendations to the Regulatory Official to approve or disapprove the submittal. The evaluation of the SRD will be an objective, unbiased assessment of the Contractor's information based on the criteria in this guidance document (Guide).

The reviewers should familiarize themselves with this Guide prior to initiating the review. The Guide is organized around the SRD Approval Criteria listed in Section 4. Sections 1 and 2 provide the introduction and purpose of the Guide, respectively. Section 3 defines the use of attributes for evaluating the Contractor's submittal. Section 5 describes the Acceptability Review. Sections 6-10 provide specific guidance for the Detailed Review of the SRD and identify attributes the RU considers important and which constitute its expectations for the substance of the SRD. The reviewers may note that this Guide appears redundant in that many requirements and SRD Approval Criteria are repeated in the various sections. This has been done deliberately so that each review section can be used as stand-alone guidance.

2. Purpose

This Guide incorporates the requirements for submittal of the SRD in the regulatory documents,¹ which are part of the Contract, and utilizes these sources for instructions to assist the reviewers in their evaluation of the SRD.

3. Attributes

This Guide uses "attributes" as review considerations for evaluating the Contractor's submittal against specific requirements. The attributes describe considerations which the reviewers may use to reach conclusions about the acceptability of the submittal. The attributes listed may not be exhaustive. The reviewers may invoke other considerations in the review in accordance with the Reviewer's experience and expertise. These considerations should be germane to the requirements being addressed and consistent with the intent of the specific review.

4. SRD Approval Basis - SRD Approval Criteria

The SRD Approval Criteria are contained in the *Regulatory Process* and are the basis for the

¹ *Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors (Regulatory Concept)*, DOE/RL-96-0005,

DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors (Regulatory Process), DOE/RL-96-0003,

Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors (Top-Level Standards), DOE/RL-96-0006, and

Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization (Standards Identification Process), DOE/RL-96-0004.

SRD approval decision. These criteria state:

The approval of the Contractor's recommended set of radiological, nuclear, and process safety standards will be issued upon determination by the Director of the Regulatory Unit [the Regulatory Official] that:

- 1) The set documented in the SRD includes all requirements of applicable laws and regulations;
- 2) The set documented in the SRD conforms to the top-level radiological, nuclear, and process standards and principles contained in the DOE-provided document titled *Top-Level Radiological, Nuclear, and Process (Safety) Standards and Principles for TWRS Privatization Contractors*, DOE/RL-96-0006, Revision 0;
- 3) The hazards associated with the proposed facility and its operation are appropriately assessed;
- 4) The set documented in the SRD was generated through the appropriate implementation of the standards process stipulated by DOE in the document titled *Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization*, DOE/RL-96-0004, Revision 0;
- 5) Appropriate expertise was employed in the standards selection and confirmation processes; and
- 6) The set documented in the SRD will provide adequate safety if properly implemented.²

5. SRD Review Approach

The reviewers will evaluate the material submitted³ by the Contractor to formulate a set of detailed review conclusions that facilitate an approval/disapproval determination consistent with the SRD Approval Criteria listed in Section 4. The overall flow of the review and the related sections are shown in Figure 5-1.

The review has two major components: 1) a process component that addresses the integrity with which the Contractor implemented the DOE-stipulated standards identification process⁴ and 2) a technical component that addresses the technical adequacy of the Contractor's hazards control approach, conformance to the top-level safety standards and principles, and compliance to laws and regulations. The process component of the review (Section 7) should be structured to directly address the seven Essential Process Steps⁵ required to be performed by the Contractor. Figure 5-2 shows the relationships between these Essential Steps. The

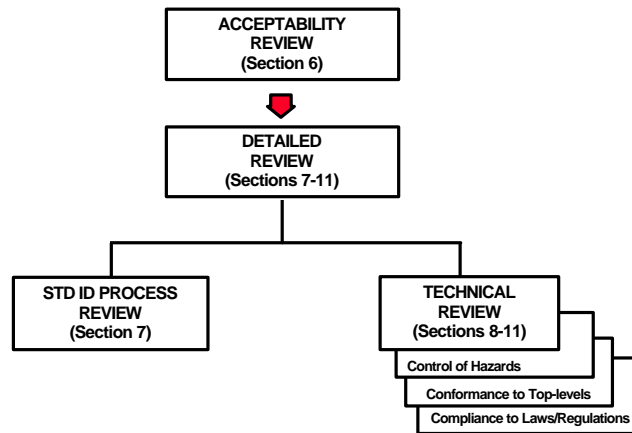
² *Regulatory Process*, Section 3.3.1, pp. 4-5.

³ *Ibid*, Section 4.1.2, pp. 11-12.

⁴ *Standards Identification Process*

⁵ *Ibid*, Section 3.1, p. 3.

aspects of the approach⁶ for Steps are described in



acceptable implementing these the *Standards*

Figure 5-1. Overall review flow

Identification Process, and information on the Contractor's implementation of this process is required as part of the SRD.⁷

The technical component of the review should address the adequacy of the standards that the Contractor has selected and recommended for achieving adequate control of radiological, nuclear, and process hazards associated with each Contractor-defined process element (component, subsystem, system, region within the facility, etc.). The approach used to review the acceptability of standards for each process element is shown in Figure 8-1. The integrated technical review should determine the:

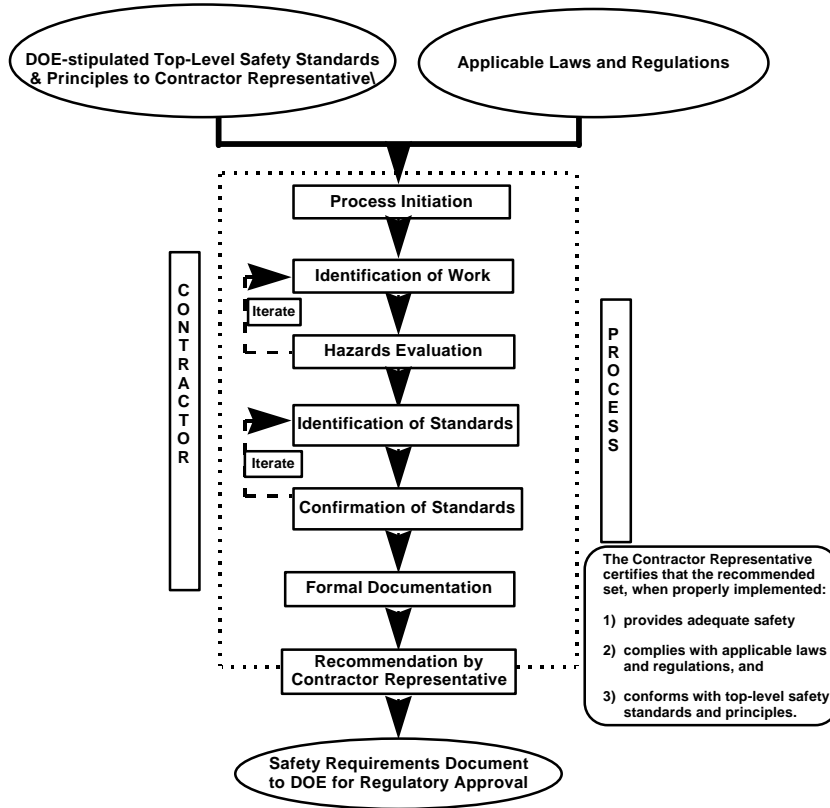
1. Adequacy of the process/system description to support hazards assessment.
2. Adequacy of the hazards assessment, including identification and characterization of the hazards.
3. Adequacy of the hazards control strategy, including conformance to the top-level safety standards and principles, and compliance to applicable laws and regulations.
4. Adequacy of standards to achieve control of the hazards, including conformance to the

⁶ *Ibid*, Table 1, pp. 4-5.

⁷ *Regulatory Process*, Section 4.1.2, pp. 11-12 .

top-level safety standards and principles, and compliance to applicable laws and regulations.

Section 8
these
elements.
required to
informatio
is relevant
review
integrated
also
with the
identificati
the
required to



elaborates on
technical review
The Contractor is
provide
n in the SRD that
to this generic
approach. This
technical review is
directly consistent
standards
on process that
Contractor is
follow.

Figure 5-2. Contractor's Process Steps to Develop Recommended Set of Standards⁸

The hazards identified for a particular process element should each be reviewed in accordance with the generic review approach described above. The reviewers should draw the relevant information from the Contractor's submittal, summarize it as it applies to the elements of the generic review approach, perform the evaluation in accordance with this Guide, and formulate and document the evaluation conclusions. The conclusions from the application of the reviews associated with all the significant hazards of the particular process element should be aggregated and integrated to formulate review conclusions for the process element as a whole.

A second level of integration should be performed across the process elements to formulate the overall technical conclusions for the SRD. These overall conclusions should address the acceptability of hazards assessment, hazards control, and hazards-control standards (Section 8); acceptability of conformance to top-level safety standards and principles (Section 9); and acceptability of compliance to applicable laws and regulations (Section 10).

Based on all of the aggregated, integrated, and cross-cutting review conclusions, the overall findings on satisfaction of the elements of the SRD Approval Criteria should be formulated. In turn, these findings should provide the basis for a recommendation to the Regulatory Official to approve or disapprove the set.

6. SRD Acceptability Review

This Guide uses the term "acceptability review" to describe the review of the SRD for completeness and adequacy. The acceptability review is mandated in the *Regulatory Process*, which states that the Standards Review for completeness and adequacy be performed within one week from the day of its receipt.⁹

In performing the SRD acceptability review, the reviewers determine whether the material is in a form that is reviewable by the RU and incorporates the requirements established in the Contract.¹⁰ If these considerations are satisfied, then the SRD is acceptable for the Detailed Review. Acceptability for the detailed review does not imply approval of the SRD.

The reviewers will evaluate each submittal requirement of the SRD for completeness and adequacy based upon the attributes cited below and document their findings. If the Contractor has generally provided information that addresses each of these attributes, the submittal can be considered complete. If specified attributes are not addressed, the reviewers will determine whether the missing information is available elsewhere or is needed to conduct the detailed review. It may be appropriate for the Contractor to provide some information called for in the attributes at a later date (i.e., prior to Authorization of Construction or Operation).

⁸ *Standards Identification Process*, Figure 1, p. 6.

⁹ *Regulatory Process*, Section 4.1.3, item 3, p. 12.

¹⁰ *Ibid*, Section 4.1.2, p. 11 (Contract requirements).

Completeness and Adequacy Attributes for Each of the SRD Required Documentation

6.1 Standards

a. Submittal Requirement

The Contractor's recommended set of radiological, nuclear, and process standards for design, construction, operation, deactivation, and regulatory submittals [are] in the form of a SRD.¹¹

b. Attributes

- Radiological, nuclear, and process standards for design, construction, operation, deactivation, and regulatory submittals are identified.
- The recommended set of standards is in the form of an SRD.

6.2 Process and Facility Description

a. Submittal Requirement

Description of the process and facility design and its proposed operation.¹²

b. Attributes

- Processes, systems, facility, and site are defined and described.
- Operational scenario, status of design, and uncertainties are defined and described.
- Work descriptions to support hazards identification and characterization are provided.
- Off-normal operational scenarios are described.

6.3 Hazards Assessment

a. Submittal Requirement

The hazards assessment used to facilitate the selection of the standards.¹³

b. Attributes

- The hazards assessment described includes the following:

¹¹ *Ibid*, item 1.

¹² *Ibid*, item 5.

¹³ *Regulatory Process*, Section 4.1.2, item 3, p. 11.

- Hazards characterization
- Assessment scope
- Assessment results
- Assessments Bases
- Risk-informed judgments
- A graded approach.

6.4 Hazards Control Strategies

a. Submittal Requirement

The hazards control strategy implemented in the design and proposed operation.¹⁴

b. Attributes

- Control Strategies have been selected and described.
- The basis for selection of the hazards control strategies is provided.
- Structures, Systems, and Components (SSC's) important to hazards control have been selected and described.
- Evidence is presented that decisions were risk-informed.
- Top-level safety standards and principles were addressed.
- Control strategies are linked explicitly to the hazards.
- Safety functions are defined (e.g., limit release of radionuclides).
- Logic is provided to mitigate hazards to acceptable ranges.

6.5 Identification Process

a. Submittal Requirement

The standards identification process used and the credentials of the participants.¹⁵

b. Attributes

- The Standard Approval Process should described the following:

¹⁴ *Ibid*, item 4.

¹⁵ *Regulatory Process*, Section 4.1.2, item 8, p. 11.

- Identification of Work
- Hazards Evaluation
- Identification of Standards
- Confirmation of Standards
- Formal Documentation
- Recommendation by Contractor Representative
- Participant Credentials.

6.6 Rationale and Justification

a. Submittal Requirement

The rationale for the selection of the standards and the adequacy of the set.¹⁶

b. Attributes

- The rationale for the selection of the standards is provided.
- The rationale for the adequacy of the set of standards is provided.
- Justification is provided for why the set of standards will:
 - Provide adequate safety
 - Comply with all applicable laws and regulations
 - Conform to top-level safety standards and principles.

6.7 Confirmation Process

a. Submittal Requirement

The standards confirmation process used and the credentials of the participants.¹⁷

b. Attributes

- The confirmation process described includes the following:
 - Team Charter or Approach

¹⁶ *Ibid*, item 7.

¹⁷ *Regulatory Process*, Section 4.1.2, item 9, p. 11.

- Team Findings
- Participant Credentials

6.8 Standards and Principles

a. Submittal Requirement

The Contractor's treatment of the top-level radiological, nuclear, and process safety standards and principles.¹⁸

b. Attributes

- Treatment of all top-level Safety Standards and Principles is described and basis for conformance is provided.

6.9 Approval Process

a. Submittal Requirement

The Contractor's approval process used for the set of standards and the basis for the approval.¹⁹

b. Attributes

- The approval process described includes the following:
 - Assurance that the Standards Identification Process was followed.
 - Assurance of Adequate Safety
 - Assurance of Conformance to Top-Level Safety Standards and Principles
 - Assurance of Compliance to Applicable Laws and Regulations
 - Assurance of Ability to Implement the Standards Set.

6.10 Certification

a. Submittal Requirement

The Contractor's certification that the set of radiological, nuclear, and process standards in the SRD will, when implemented, provide adequate safety, comply with all applicable laws and regulations, and conform to the DOE-stipulated top-level safety standards and principles.²⁰

¹⁸ *Ibid*, item 6.

¹⁹ *Ibid*, item 10, p. 12.

²⁰ *Regulatory Process*, Section 4.1.2, item 2, p. 11.

b. Attributes

- The signatory has the legal authority to sign for the company.
- The certification for contractual commitments is notarized.
- Certification states that the Contractor commits to implementing the SRD.
- The Contractor certifies that the SRD, when implemented will:
 - provide adequate safety.
 - comply with all applicable laws and regulations.
 - conform to the top-level safety standards and principles.

The Acceptability Review is not a detailed review. In areas where significant information needed by the RU is missing, the information shall be requested. Upon completing the review, a letter is issued to the Contractor regarding the acceptability of the package. If the package is rejected, the RU will provide the reasons for the rejection and the necessary corrective actions. After the package is accepted for review, the RU may request additional information from the Contractor to clarify or supplement material in the package. Acceptability for the Detailed Review does not imply approval of the SRD.

7. Standards Identification Process Review - Seven Essential Steps

A key feature of this process is that [these] standards for performance of work link directly to specific radiological, nuclear, and process hazards associated with that work. Additionally, the use of experts and participation by stakeholders will ensure credibility, completeness, and adequate protection of workers, the public, and the environment.²¹

The reviewers should focus on the adequacy of the execution of the *Standards Identification Process*, not on the technical adequacy of the results to control hazards, which is the subject of Section 8. The reviewers should evaluate whether the process described is logical, structured, and disciplined. Adequate implementation of the *Standards Identification Process* is dependent on the use of individuals having the necessary credentials to both lead and participate in the process.

The Essential Process Step, Performers, and Acceptable Approach from the *Standards Identification Process* are listed in this Guide. The Acceptable Approach is the approach against

which the submittal will be reviewed. The reviewers should consider both the Essential Process Steps and the Attribute information in the review.

Submittal Requirements

The Contractor's Standards Approval documentation shall include the standards identification

²¹ *Standards Identification Process*, Section 3, p. 3.

process used and the credentials of the participants.²²

Although the Contractor Representative may deviate from the Acceptable Approach, the Contractor Representative shall ensure that the process used meets the concepts of DOE M 450.3-1.²³

Table 1 (*Standards Identification Process*) lists the steps of the process necessary to develop a recommended set of radiological, nuclear, and process safety standards. The Essential Process Steps listed in the first column shall be performed by the Contractor to ensure that the process is performed in a manner consistent with DOE's Standards Program.²⁴

The set documented in the SRD was generated through the appropriate implementation of the standards process stipulated by DOE in the document titled *Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization*, DOE/RL-96-0004, Revision 0.²⁵

Appropriate expertise was employed in the standards selection and confirmation process.²⁶

7.1 Process Initiation

The Process Initiation step (Table 7-1) involves putting in place all those measures that guide, define, and staff the standards identification process. The reviewers should determine if the Contractor has adequately executed this "Essential Process Step." Process Initiation shall be reviewed against the Acceptable Approach. The reviewers should consider the additional attributes provided.

Attribute 1 - Selection of Individuals^a

The basis for the selection of the process manager and various teams for implementing the *Standards Identification Process* is described.

Attribute 2 - Process Description^b

The process used to select its set of standards is described in a charter and implementation plan. The description should include a discussion of conformance to the Essential Process Steps outlined in the *Standards Identification Process*.

²² *Regulatory Process*, Section 4.1.2, item 8, p. 11.

²³ *Standards Identification Process*, Section 3.1, p. 3.

²⁴ *Ibid.*

²⁵ *Regulatory Process*, Section 3.3.1, item 4, p. 4.

²⁶ *Ibid.*, item 5.

Table 7-1. Process Initiation²⁷

ESSENTIAL PROCESS STEP	PERFORMERS	ACCEPTABLE APPROACH
1. Process Initiation	<ul style="list-style-type: none"> CR PM PMT Stakeholders RMRU 	<ul style="list-style-type: none"> CR designates PM and PMT CR provides charter and delegates authority to PM and PMT to implement this standards process PM prepares implementation plan including team staffing requirements, team operating procedures, outputs required, documentation required PM prepares rosters (candidates & credentials) PMT approves plans, rosters, and procedures PM mobilizes the process activities Stakeholders invited and encouraged to provide input and express views to PM and PMT RMRU attends any meetings that will facilitate early gathering of information on process

Attribute 3 - Identification of Process Scope and Objectives^c

The charter and implementation plan used for the process ensure that the process identifies a complete set of standards. That is, the standards that 1) address the DOE stipulated top-level safety standards and principles; 2) include applicable rules, regulations, and requirements; and 3) address the hazards.

Attribute 4 - Process Infrastructure

The team staffing requirements, team operating procedures, outputs required, and documentation required are provided.

Attribute 5 - Management Credentials^d

The credentials of the process manager and each member of the process management team, and an evaluation of these credentials against the team staffing requirements, are provided.

Attribute 6 - Identification Team Credentials^e

The credentials of each member selected to serve on the standards identification team, and an evaluation of these credentials against the team staffing requirements are provided. The reviewers should also consider whether records of each member's: 1) training for the specific

²⁷ *Standards Identification Process*, Table 1, p. 4.

work to be performed and similar work, 2) work experience on relevant projects and an indication

of the success of those projects, 3) involvement in other standards committees, and 4) technical training such as degrees and specialized training are provided.

Attribute 7 - Delineation of Assignments^f

A delineation of specific areas for which the individual had responsibilities is provided for each member of the standards identification team.

Attribute 8 - Standards Selection Criteria^g

The logic that was used to select the individual standards is described. This decision logic should include the Contractor's application of graded approach, and balanced approach for controlling various hazards, as well as the DOE stipulated top-level safety standards and principles.

Attribute 9 - Stakeholder Involvement^h

Stakeholder involvement in the standards development process is described.

Attribute 10 - Process for Developing and Validating Ad Hoc Standardsⁱ

The process used for developing and validating ad hoc standards when nationally recognized standards are either not available or not appropriate is described.

Attribute 11 - Incorporation of Changes in the Design and Hazards Assessment^j

The process for incorporating changes in the facility design, proposed operations, and hazards assessment into the standards identification process is described. Triggers for re-evaluating the standards set based on the nature and magnitude of the changes should be described.

Attribute 12 - Consistency of SRD with Sources^k

The process for ensuring consistency among the design information, hazards assessment, hazards controls, and selected standards at the time the SRD is completed and submitted to the RU for review is described.

7.2 Identification of the Work

The Identification of Work step (Table 7-2) involves identifying and describing key systems, structures, components, and operations.

Submittal Requirement

The Contractor's Standards Approval documentation shall include a description of the process and facility design and its proposed operation.²⁸

²⁸ *Regulatory Process*, Section 4.1.2, item 5, p. 11.

The reviewers should determine if the Contractor has adequately executed this “Essential Process Step.” Identification of Work shall be reviewed against the Acceptable Approach.

Table 7-2. Identification of Work²⁹

ESSENTIAL PROCESS STEP	PERFORMERS	ACCEPTABLE APPROACH
2. Identification of Work	<ul style="list-style-type: none"> • PM • DC • WAE • PMT • RMRU 	<ul style="list-style-type: none"> • PM manages the Step-2 activities • DC provides technical/contractual scope support • WAE define overall processes • WAE identify and describe key systems, structures, components, and operations • WAE document the work activities • PMT provides technical resource consultation • PM proposes additional experts as needed • PMT approves additional experts as needed • PMT monitors the Step-2 activities • RMRU attends any meetings that will facilitate early gathering of information on process

7.3 Hazards Evaluation

Hazards evaluation involves the performance of hazards analysis and assessing measures for control of the hazards. The Contractor’s Hazards Evaluation process (Table 7-3) is the subject of this review.

Submittal Requirement

The Contractor’s Standards Approval documentation shall include a hazards assessment used to facilitate the selection of the standards.³⁰

The reviewers should determine if the Contractor has adequately executed this “Essential Process Step.” The reviewers shall evaluate the Contractor’s hazards evaluation against the Acceptable Approach. The reviewers should also consider the additional attributes provided.

Attribute 1 - Methodology¹

²⁹ *Standards Identification Process*, Table 1, p. 4.

³⁰ *Regulatory Process*, Section 4.1.2, item 3, p. 11.

The hazards analysis approach/methodology used to identify and characterize the hazards associated with its planned waste processing activities is described. The description should include methodology, selection criteria for participants, and justification for the selection of the approach.

Table 7-3. Hazards Evaluation³¹

ESSENTIAL PROCESS STEP	PERFORMERS	ACCEPTABLE APPROACH
3. Hazards Evaluation	<ul style="list-style-type: none"> • PM • WAE • HAE • PMT • RMRU 	<ul style="list-style-type: none"> • PM manages the Step-3 activities • WAE provide consultation on work elements • HAE identify and describe work hazards • HAE define a hazard assessment approach • HAE assess work hazards • HAE document the hazards assessment • PMT provides technical resource consultation • PM proposes additional experts as needed • PMT approves additional experts as needed • PMT monitors the Step-3 activities • RMRU attends any meetings that will facilitate early gathering of information on process

Attribute 2 - Hazards Characterization^m

The Contractor's hazards assessment produces results that allow standards-based judgments to be made on the need for, and importance of, hazards controls. Further, the results should address the Contractor's facility workers, Hanford Site workers, the public, and environmental pathways to the public.

Attribute 3 - Assessment Resultsⁿ

The results of the Contractor's identification, analysis, and characterization of the hazards for its tank waste processing activities are clearly presented. The results should include the full spectrum of results showing the distribution of hazards in the facility for various operational states, the distribution of identified hazardous events by severity and hazard type, and the categories of hazards that require differing levels of controls because of their risk implications.

7.4 Identification of Standards

³¹ *Standards Identification Process*, Table 1, p. 4.

The Identification of Standards involves the Contractors integration of the results of hazards evaluation, the requirement to conform to the top-level safety standards and principles, and the requirement to comply with the applicable laws and regulations into a standards selection process.

Submittal Requirements

The Contractor's Standards Approval documentation shall include:

- Hazards control strategy that will be implemented in the design and proposed operations³²
- The Contractor shall submit a rationale for the selection of the standards and the adequacy of the set.³³

The reviewers should determine if the Contractor has adequately executed this "Essential Process Step." The reviewers shall evaluate the Contractor's Identification of Standards process against the Acceptable Approach. In addition, the reviewers should consider the additional attributes provided.

Table 7-4. Identification of Standards³⁴

ESSENTIAL PROCESS STEP	PERFORMERS	ACCEPTABLE APPROACH

³² *Regulatory Process*, Section 4.1.2, item 4, p. 11.

³³ *Ibid*, item 7.

³⁴ *Standards Identification Process*, Table 1, p. 5.

4 Identification of Standards	<ul style="list-style-type: none"> • PM • WAE • HAE • HCE • ESE • PMT • RMRU 	<ul style="list-style-type: none"> • PM manages the Step-4 activities • WAE provide consultation on work elements • HAE provide consultation on work hazards • HCE delineate hazards control approaches • ESE select appropriate standards based on the Step 2 & 3 results and hazards control approaches • ESE prepare justifications of standards selections and identify any legal requirements and top-level (safety) standards and principles that do not add value • ESE/PM document the set of selected standards • PMT provides technical resource consultation • PM proposes additional experts as needed • PMT approves additional experts as needed • PMT monitors the Step-4 activities • RMRU attends any meetings that will facilitate early gathering of information on process
-------------------------------	---	--

Attribute 1 - Selected Control Strategies^o

The selected control strategy for each hazard or class of hazards are described in terms of the safety functions required (i.e., limit release of radionuclides, etc.) and in terms of the set of design features, administrative controls/procedures, and management systems selected for implementing the strategy. This material should provide direct linkage between control strategy and hazard.

Attribute 2 - Structures, Systems, and Components (SSCs) Important to Hazards Control^p

The SSCs that will be relied upon for implementing the strategy are based on the control strategy selected and are listed. This material should provide direct linkage between the control strategy and associated SSCs.

Attribute 3 - Control Strategy Options^q

If at the time the hazard control strategy is submitted, the Contractor still has several control strategies under consideration for a given hazard or class of hazards, the reviewers should consider whether these options are clearly described in the same manner as those reviewed in the "Selected Control Strategies" attribute above. Further, the reviewers should consider whether one of the options is designated as the Contractor's reference approach for purposes of the SRD review.

Attribute 4 - Justification Scope^r

The standards that were selected are documented and their selection justified. The reviewers

should not expect the Contractor to submit documentation that justifies the reasons all other standards were not selected. Appropriate linkage between each selected standard or requirement to its role in the control of hazards or satisfaction of rules, regulations, or contract requirements should be provided.

Attribute 5 - Justification Basis^s

The justification of the selection of each standard or requirement is based on the merits of its intended contribution to a specified hazard control function or satisfaction of rules, regulations, or contract requirements. Therefore, for each selected standard or requirement, the reviewers should consider whether the intended purpose of the selected standard or requirement is described and whether the selection fulfills that purpose. The reviewers should consider whether the reliance on standard precedents is evident (e.g., endorsed by DOE or NRC, nationally recognized and endorsed, proven by internal use, etc.).

7.5 Confirmation Process

The Confirmation Process involves the managed process for confirming the adequacy of the set of recommended standards. Adequate confirmation is dependent on the use of individuals having the necessary credentials. An Independent Review Team (IRT) is to be used by the Contractor to confirm the set of proposed standards and requirements. The confirmation process step is important to providing assurance that the Contractor's selected set of standards and requirements are complete, appropriate, and adequate. The adequacy of the Confirmation Process (Table 7-5) is the subject of this review.

Submittal Requirement

The Contractor's Standards Approval documentation shall include a Description of the standards confirmation process used and the credentials of the participants.³⁵

Appropriate expertise was employed in the standards selection and confirmation processes.

The reviewers should determine if the Contractor has adequately executed this "Essential Process Step." The Confirmation Process shall be reviewed against the Acceptable Approach. The reviewers should consider the additional attributes provided.

In the event that the confirmation process identifies a need to re-examine one of the standards identified by the ESH Standards Expert/Process Management (ESE/PM), the Contractor should provide documentation describing the iterations that occurred between the ESE/PM and the IRT which lead to standard selection.

Table 7-5. Confirmation of Standards³⁶

ESSENTIAL PROCESS STEP	PERFORMERS	ACCEPTABLE APPROACH

³⁵ *Regulatory Process*, Section 4.1.2, item 9, p. 11.

³⁶ *Standards Identification Process*, Table 1, p. 5.

5 Confirmation of Standards	<ul style="list-style-type: none"> •PM •CR •IRT •PMT •Stakeholders •RMRU 	<ul style="list-style-type: none"> • PM manages the Step-5 activities • PM facilitates IRT activities by providing documentation, information briefings, and discussion meetings • CR designates the IRT • IRT defines its review/confirmation approach • IRT performs its review • IRT documents its approach and findings • IRT provides comments to the PM for revision of the set of selected standards and associated documentation • PMT monitors the Step-5 activities • Stakeholders invited and encouraged to provide input and express views to PM and PMT • RMRU attends any meetings that will facilitate early gathering of information on process
-----------------------------	--	---

Attribute 1 - Team Charter^t

The charter under which the IRT operated is provided. The charter should include the team's scope, objectives, and responsibilities.

Attribute 2 - Team Qualification and Training^u

The selection criteria and required qualifications and training for members of the IRT has been provided. Consideration should have been given to including an appropriate DOE (non-RU) member on this team. A description of the independence of the team should be included.

Attribute 3 - Delineation of Assignments

Records are provided for each member of the IRT that delineate specific areas for which the individual is responsible.

Attribute 4 - IRT Credentials^v

The records are provided confirming that IRT members have been qualified and adequately trained along with the technical credentials of each member selected to serve on the IRT. A description of their work experience on relevant projects and an indication of the success of those projects (and the individual's positive contribution) also should be included. Any involvement in standards committees should be indicated. In addition, their technical training such as degrees and specialized training should be described.

Attribute 5 - Process Description^w

The process used to confirm the adequacy of the selected set of standards and requirements has been described. The description should include a discussion of how conformance to the Essential Process Steps outlined in the *Standards Identification Process* was confirmed. The Contractor should describe stakeholder involvement in the process.

Attribute 6 - Team Findings^x

A copy of the IRT's findings and comments is provided. The findings should address the integrity of the selection process as well as an assessment of whether the selected set is adequate. Perceived difficulties in implementing the standards in the design and operation of the facility also should be addressed. If minority reports or stakeholder comments are developed separately, they also should be submitted.

Attribute 7 - Disposition of Findings^y

The reviewers should consider how each finding and comment received from the IRT was dispositioned. If minority reports or stakeholder comments are received separately, the dispositioning of these comments also should be described.

7.6 Formal Documentation

Formal documentation (Table 7-6) provides a record of completion of the *Standards Identification Process*, verification that the standards identification process and objectives have been met, and completion of Contractor approval.

Submittal Requirement

The Contractor's Standards Approval documentation shall include the approval process used for the set of standards and the basis for the approval.³⁷

The reviewers should determine if the Contractor has adequately executed this "Essential Process Step." The Formal Documentation shall be reviewed against the Acceptable Approach. The reviewers should consider the additional attributes provided.

Table 7-6. Formal Documentation³⁸

ESSENTIAL PROCESS STEP	PERFORMERS	ACCEPTABLE APPROACH

³⁷ *Regulatory Process*, Section 4.1.2, item 10, p. 12.

³⁸ *Standards Identification Process*, Table 1, p. 5.

6. Formal Documentation	<ul style="list-style-type: none"> • PMT • PM • CR 	<ul style="list-style-type: none"> • PMT verifies the overall process implementation • PM prepares draft of submittal required by Director of the Regulatory Unit (Safety Requirements Document and supporting information) • PMT reviews the draft submittal • PM recommends final submittal to CR • CR approves the final submittal
-------------------------	---	--

Attribute 1 - Approval Process Description^z

The process used to approve the selected set of standards is provided.

Attribute 2 - Assurance of Process Implementation^{aa}

The Contractor's approval addresses the adequacy of the standards selection and confirmation processes and their implementation.

Attribute 3 - Assurance of Adequate Safety^{bb}

The Contractor's approval addresses the adequacy of the standards set in terms of providing adequate safety, when properly implemented.

Attribute 4 - Assurance of Adequacy Conformance to Top-Level Safety Standards and Principles^{cc}

The Contractor's approval addresses the adequacy of the standards set in terms of providing adequate conformance to the DOE-stipulated top-level safety standards and principles, when properly implemented.

Attribute 5 - Assurance of Adequacy Compliance to Applicable Laws and Regulations^{dd}

The Contractor's approval addresses the adequacy of the standards set in terms of providing adequate compliance to the applicable laws and regulations, when properly implemented.

Attribute 6 - Assurance of Ability to Implement the Standards Set^{ee}

The basis used to ensure that the selected standards can be implemented in the design and operation of the facility is provided.

7.7 Certification

The Certification (Table 7-7) ensures that standards in the SRD represent the Contractor's commitment to the sufficiency of the set from the standpoints of providing adequate safety, complying with all applicable laws and regulations, and conforming to the DOE-stipulated top-

level safety standards and principles.

Submittal Requirement

The Contractor's Standards Approval documentation shall include a certification that the set of radiological, nuclear, and process standards in the SRD will, when implemented, provide adequate safety, comply with all applicable laws and regulations, and conform to the DOE-stipulated top-level safety standards and principles.³⁹

The reviewers should determine if the Contractor has adequately executed this "Essential Process Step." Certification shall be reviewed against the Acceptable Approach. The reviewers should consider the additional attributes provided.

Table 7-7. Recommendation by Contractor Representative(Certification)⁴⁰

ESSENTIAL PROCESS STEP	PERFORMERS	ACCEPTABLE APPROACH
7. Recommendation by CR	<ul style="list-style-type: none"> CR 	<ul style="list-style-type: none"> CR certifies the set of standards contained in the final submittal is adequate and provides submittal to Director of the Regulatory Unit

Attribute 1 - Contractual Agreement^{ff}

The Contractor provided a written certification that states that the set of radiological, nuclear, and process standards in the SRD will, when implemented, provide adequate safety, comply with all applicable laws and regulations, and conform to the DOE-stipulated top-level safety standards and principles. In addition, the reviewers should consider that this certification constitutes a contractual commitment by the Contractor in partial fulfillment of the terms of its current TWRS Privatization Contract with DOE. The certification and recognition of the more defined contractual commitment should be in a notarized letter from the Contractor.

Attribute 2 - Signatory's Authority^{gg}

The Contractor described the signatory's legal authority to act on behalf of the Contractor corporation.

³⁹ *Regulatory Process*, Section 4.1.2, item 2, p. 11.

⁴⁰ *Standards Identification Process*, Table 1, p. 5.

8. Technical Review of Hazards Control

The reviews in this section focus on the technical adequacy of the identified standards and the technical justification for providing adequate control of the hazards, when properly implemented. The review should be systematically performed by considering each hazard in a Contractor-defined process element (component, subsystem, system, portion of the facility, etc.) and by evaluating the proposed control of that hazard in an integrated manner as shown in Figure 8-1. For each hazard, the review should address the following topics:

1. Adequacy of the process/system description to support hazards assessment.
2. Adequacy of the hazards assessment, including identification and characterization of the hazards.
3. Adequacy of the hazards control strategy, including conformance to the top-level safety standards and principles, and compliance to applicable laws and regulations.
4. Adequacy of standards to achieve control of the hazards, including conformance to the top-level safety standards and principles, and compliance to applicable laws and regulations.

Evaluation statements should consist of 1) an overall conclusion on adequacy along with the basis for the conclusion in terms of materials cited, requirements met or not met and why; and 2) a concise statement of actions necessary to reach adequacy if a negative conclusion is reached

To facilitate view, dance is ovided Sections 1 ough 4.

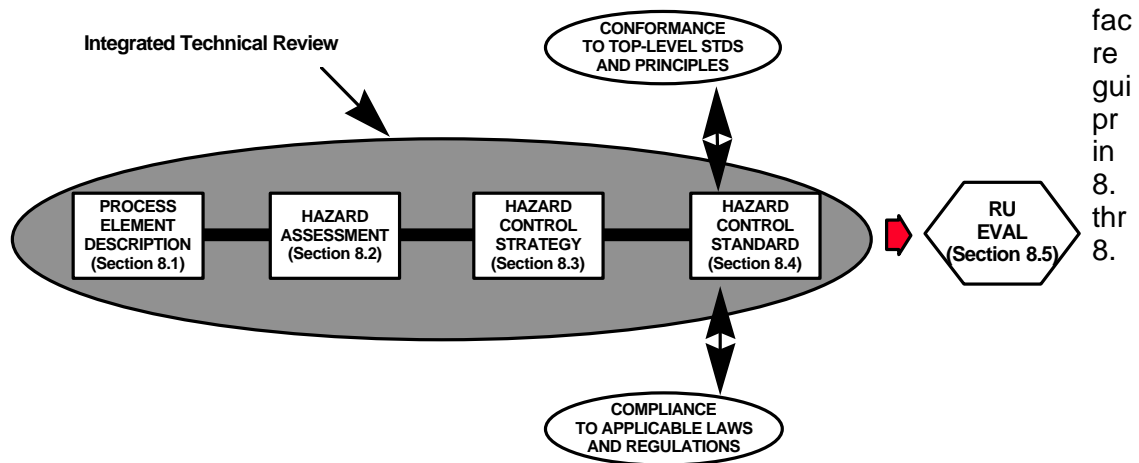


Figure 8-1. Integrated Technical Review of Standards

When all significant hazards identified by the Contractor for the process element have been addressed, evaluations should be performed for the process element as a whole and then for the Contractor's entire waste processing facility. The integration of process-element evaluation results should start with a tabulation (See Exhibit 8-1) of the results from the reviews at the process element level. Integrated evaluation statements should be formulated emphasizing inadequacies and actions needed to achieve adequacy. Section 8.5 provides further guidance on integration of review results and evaluation conclusions.

Submittal Requirements

The hazards associated with the proposed facility and its operation are appropriately assessed.⁴¹

The set documented in the SRD will provide adequate safety if properly implemented.⁴²

8.1 Process Element Description

This segment of the review determines the adequacy of process element description to provide a documented basis for hazards identification and characterization, hazards control (features selected to provide protection for the facility workers, co-located workers, and the public), and selection of standards for implementing the hazards control.

Submittal Requirement

The Contractor's Standards Approval documentation shall include a description of the process and facility design and its proposed operation.⁴³

The reviewers should identify and evaluate the descriptive materials in the Contractor's SRD that relate to the particular process element (component, subsystem, system, portion of the facility, etc.) being reviewed. If the descriptive material is found to be incomplete or unclear, the reviewer(s) should prepare requests for additional information.

Attribute 1 - Process Descriptions^{hh}

The Contractor's descriptions of its planned tank waste treatment processes include the basic functions and theories of each process in sufficient detail to support hazards identification, hazards characterization, and risk-informed decision making to control the hazards.

Attribute 2 - Systems Descriptionsⁱⁱ

The Contractor's descriptions of planned tank waste treatment systems include the basic functions of the systems, the key components/equipment involved (e.g., sizes, inventories, etc.), operating characteristics (e.g., batch, continuous, chemicals involved and their

⁴¹ *Regulatory Process*, Section 3.3.1, item 3, p. 4.

⁴² *Ibid.*, item 6, p. 5.

⁴³ *Ibid.*, Section 4.1.2, item 5, p. 11.

concentrations, radionuclides involved and their concentrations, etc.), and approximate operating ranges and limits (e.g., pressures, temperatures, processed material states, flow rates, etc.), and are sufficient to support hazards identification, hazards characterization, and risk-informed decision making to control the hazards.

Attribute 3 - Facility Description^{jj}

The Contractor's description of the facility includes the purpose and function of each building, design information regarding the facility's resistance to the effects of external events, location and arrangement of the buildings on the site and their distance from the facility fence and the site boundary, and other features (if any) that could affect hazards identification, hazards characterization, and risk-informed decision making to control the hazards.

Attribute 4 - Site Description^{kk}

The Contractor's description of the site includes, as appropriate, the site geography, demography, meteorology, hydrology, geology, and seismology sufficient to support hazards identification, hazards characterization, and risk-informed decision making to control the hazards. Man-made external events that contribute to the hazards to the facility workers or could contribute to the "release" of the hazards associated with the facility should be included. If information from sources at the Hanford Site is used, it should be referenced. The characteristics of and rationale for the selected external events and selected receptors should be included.

Attribute 5 - Operational Scenarios^{ll}

The Contractor's description of the intended operational scenarios includes normal operations and anticipated events (internal and external), sufficient to support hazards identification, hazards characterization, and risk-informed decision making to control the hazards. This description should include startup, shutdown, maintenance/equipment change-out, processing cycles (if batch-type), and off-normal events, particularly as they relate to hazards that differ from those associated with steady-state operation and as they relate to different deployment of operating personnel.

Attribute 6 - Design Status^{mm}

The Contractor's identification of work based upon the maturity of design is anticipated to change in a manner sufficient to invalidate the hazard assessment.

Attribute 7 - Uncertaintiesⁿⁿ

The Contractor's summary of uncertainties in tank waste treatment process or design addresses the potential for changing significantly the hazards-based activities that are the subject of the Standards Approval Review.

8.2 Hazards Assessment

This element of the review is to determine the adequacy of the hazards assessment (identification and characterization) for the process element to provide a documented basis for hazards control (physical features or human actions features selected to provide protection for

the facility workers, co-located workers, and the public) and standards⁴⁴ for achieving the hazards control.

Submittal Requirements

The Contractor's Standards Approval documentation shall include a hazards assessment used to facilitate the selection of the standards.⁴⁵

Consistent with applicable laws and legal requirements, the Contractor is required to tailor the exercise of this responsibility to the specific hazards associated with its activities.⁴⁶

Radiological, nuclear, and process safety requirements shall be adapted to the specific hazards that are identified with the Contractor's waste treatment services.⁴⁷

The reviewers should identify and evaluate the hazards identification and characterization submittal materials in the Contractor's Standards Approval Package and/or the Hazards Analysis Report that relates to the particular process element (component, subsystem, system, portion of the facility) being reviewed. It also deals with the significance of hazardous situations (qualitative risk to the public, facility workers, and Hanford Site workers). If the material is found to be incomplete or unclear, the reviewers should prepare requests for additional information.

Attribute 1 - Methodology^{oo}

The Contractor's hazards assessment approach includes methodology, selection criteria for participants, and justification for the selection of the approach.

Attribute 2 - Comprehensiveness^{pp}

The Contractor's hazards assessment for planned waste processing activities is comprehensive, addressing all its planned activities and associated postulated events throughout the life cycle (pre-operation testing, operational modes, deactivation, etc.).

Attribute 3 - Hazards Characterization^{qq}

The Contractor's hazards assessment results permit risk-informed judgments to be made on the need for and importance of hazards controls. Further, these same results should address the consequences to the Contractor's facility workers, Hanford Site workers, the public, and environmental pathways.

Attribute 4 - Assessment Scope^{rr}

The Contractor's hazards assessment approach identifies and characterizes a broad set of

⁴⁴ *Standards Identification Process*

⁴⁵ *Regulatory Process*, Section 4.1.2, item 3, p. 11.

⁴⁶ *Regulatory Concept*, Section 1, p. 1.

⁴⁷ *Contract*, Standard 4, item C.2(a), p. C-22.

hazards, including radiological, nuclear, toxicological, explosion, fire, falling objects, electrical, etc., which could potentially harm workers (facility and/or Site) or the public directly, or indirectly through the initiation of hazardous events and/or damage to hazard control features.

Attribute 5 - Control Strategy Facilitation^{ss}

The hazards assessment has sufficient detail to enable the use of a graded approach in the formulation of effective and efficient control strategies for each identified. The reviewers should consider the degree to which the hazard assessment results facilitate the selection of effective and efficient hazard control strategies through tailoring consistent with risk management approaches.

Attribute 6 - Assessment Results^{tt}

The Contractor's hazard assessment includes results showing the distribution of hazards in the facility for various operational states, the distribution of identified hazardous events by severity and hazard type, and the categories of hazards that require differing levels of controls because of their risk implications. The reviewers should consider the following:

- The degree to which the hazard assessment results for the process element are consistent with overall results.
- The degree to which the hazards identified and characterized for the process element are consistent with those for other similar process elements.
- The degree of consistency with results from other similar hazards assessments such as the Defense Waste Processing Facility Final Safety Analysis Report (DWPF FSAR), TWRS Draft Safety Analysis Report (SAR), West Valley Demonstration Project (WVDP) SAR, Los Alamos National Laboratories (LANL) Preliminary Hazards Analysis (PHA) for Privatization^{uu} (completeness and technical reasonableness of types of hazards, their likelihoods, their consequences, and their risk binning).
- The reasonableness of the events defined that deliver hazards to various receptors.
- The reasonableness of the rationale presented by the Contractor for the qualitative likelihoods and consequences provided.
- The reasonableness of the treatment of external events.
- The reasonableness of the treatment of potential interactions among process elements.

Attribute 7 - Assessment Bases^{vv}

The Contractor's basis for the assessment and characterization of each hazard, as applicable, consists of hazardous material inventories at risk, release mechanisms (energy sources for example), material transportability, transport paths and assumed transport mechanisms, assumed barriers to delivery of the hazard to a designated receptor, health impact

considerations used (e.g., dose levels, toxicity of chemicals, etc.), assumed location of receptors, assumed prevention/mitigation features or measures, etc.

8.3 Hazards Control Strategies

This element of the review is designed to determine the adequacy of the hazards control strategies (physical features or human actions selected to provide protection for the facility workers, co-located workers, and the public) for the hazards associated with the process element to provide a documented basis for the standards⁴⁸ utilized in implementing the hazards control.

Submittal Requirements

The Contractor's Standards Approval documentation shall include a hazards control strategy that will be implemented in the design and proposed operations.⁴⁹

Consistent with applicable laws and legal requirements, the Contractor is required to tailor the exercise of this responsibility to the specific hazards associated with its activities.⁵⁰

The reviewers should identify and evaluate the materials on hazards control strategies in the SRD that relate to the particular process element (component, subsystem, system, portion of the facility, etc.) being reviewed. If the material is found to be incomplete or unclear, the reviewers should prepare requests for additional information.

Attribute 1 - Selected Control Strategies^{ww}

The Contractor's selected control strategy for each hazard or class of hazards consists of the safety functions required (i.e., limit release of radionuclides, etc.) and the set of design features, administrative controls, and procedures. The reviewers should assess the following:

- The general appropriateness and reasonableness of the Contractor's selected safety (protection) functions and their characterization (e.g., highly reliable for all operating modes and under accident conditions).
- The degree to which the Contractor's control strategy is consistent with achieving the safety functions specified for controlling the hazard.
- The degree to which the Contractor's control strategy for each hazard or class of hazards is consistent with, or appropriately different from, strategies used to control similar hazards in similar settings such as for DWPF FSAR and WVDP SAR or their British or French counterparts.^{xx}
- The degree to which the selected control strategies properly reflect the

⁴⁸ *Standards Identification Process*.

⁴⁹ *Regulatory Process*, Section 4.1.2, item 4, p. 11.

⁵⁰ *Regulatory Concept*, Section 1, p.1.

Contractor's decision logic, particularly tailoring and defense in depth.

- The manner in which the top-level safety standards and principles⁵¹ influenced the selection of the strategy and the appropriateness of that influence in light of the degree of acceptability (i.e., have been implemented and accepted by authoritative safety bodies) of the selected strategy for similar hazards for similar facilities.

Attribute 2 - Structures, Systems, and Components (SSCs) Important to Hazards Control^{yy}

Based on the hazard control strategy selected, the Contractor listed the SSCs that will be relied upon for implementing the strategy. The reviewers should assess the degree to which designated SSCs are consistent with the selected control strategies and conform with the Availability, Maintainability, and Inspectability Principle, which states that structures, systems, and components important to safety should be designated.⁵²

The reviewers should consider any proposed tailoring of SSCs (such as safety grade, safety significant, etc.) in light of the significance (class of receptors involved and/or the degree of intervention required--e.g., very large consequences if function fails when needed) of the associated safety function. The reviewers should assess the degree to which this tailoring is consistent with that used currently in DOE nonreactor nuclear facilities.^{zz}

Attribute 3 - Risk-informed Decision Logic^{aaa}

Based on the results of the hazards assessment, the Contractor described the basis used to determine when hazard controls were needed. The Contractor should describe what it considers an acceptably controlled hazard and what logic was used to move a hazard from an unacceptable into an acceptable range (via frequency or consequence change). The description also should include the logic for selecting from among design or administrative controls, selecting between frequency or consequence mitigation, deciding which hazards can be grouped, deciding when to invoke defense in depth, and applying the graded approach. The reviewers should consider the degree to which the Contractor's logic for determining the need for and character of hazard control strategies (functions and features) is based on the dose limits⁵³ for individuals and conforms with the Risk Assessment Principle, which states that acceptable risk analyses should be applied during the design to delineate provisions for the prevention and mitigation, including emergency preparedness and response, of otherwise risk-dominant events.⁵⁴

The reviewers also should assess the degree to which the logic for selecting the hazards control strategies is in accordance with the following top-level safety standards and principles.⁵⁵

⁵¹ *Top-Level Safety Standards and Principles*.

⁵² *Ibid*, Section 4.2.7.2, p. 11.

⁵³ *Top Level Safety Standards and Principles*, Section 2.1, pp. 2-3.

⁵⁴ *Ibid*, Section 4.2.1.2, p. 8.

⁵⁵ *Ibid*, Section 4.1.1.1, p. 6.

4.1.1.1 Defense in Depth

To compensate for potential human and mechanical failures, a defense-in-depth strategy should be applied to the facility commensurate with the hazards such that assured safety is vested in multiple, independent safety provisions, no one of which is to be relied upon excessively to protect the public, the workers, or the environment. This strategy should be applied to the design and operation of the facility.

Design features that enhance the margins of safety through simplified, inherent, passive, or other highly reliable means to accomplish safety functions should be employed to the maximum extent practical.⁵⁶

Attribute 4 - Hazards Control Balance^{bbb}

The Contractor described how a balanced approach was achieved in the control of radiological, nuclear, and process chemical hazards. That is, comparable risks that result from either radiological, nuclear or process hazards should evoke comparable levels of controls.

Attribute 5 - Utilization of Top-Level Standards and Principles^{ccc}

The Contractor described how the top-level safety standards and principles were integrated into the decision process to arrive at the selected hazard control strategies.

Attribute 6 - Control Strategy Options^{ddd}

If the Contractor still has several control strategies under consideration for a given hazard or class of hazards when the hazard control strategies are submitted, the reviewers should assess whether these options are clearly described. Further, the reviewers should determine if the Contractor designated one of the options as its reference approach in the SRD.

8.4 Hazards Control Standards

This element of the review is to determine the adequacy of the standards for implementing the hazards control strategy for the process element being reviewed. The standards to be evaluated may be either specific limits that the Contractor has adopted for the purpose of providing adequate protection in specified hazardous situations (e.g., hydrogen concentration limits to ensure protection against adverse effects of hydrogen) or may be the selected means by which hazards control strategies (in terms of physical features or human activities) are to be achieved.

Submittal Requirement

The Contractor shall submit a rationale for the selection of the standards and the adequacy of the set.⁵⁷

⁵⁶ *Ibid*, Section 4.2.5.1, p. 10.

⁵⁷ *Regulatory Process*, Section 4.1.2, item 7, p. 11.

The reviewers should identify and evaluate the materials in the SRD that relate to the selection and justification of standards for this particular process element (component, subsystem, system, portion of the facility, etc.) being reviewed. If the material is found to be incomplete or unclear, the reviewers should prepare requests for additional information.

Attribute 1 - Justification Scope^{eee}

The Contractor provided justifications for those standards selected for the purpose of controlling the hazards associated with its intended activities. There is no expectation that the Contractor document the reasons all other standards were not chosen. Appropriate linkage to the application of each selected standard or requirement to its role in the control of hazards should be provided.

Attribute 2 - Justification Basis^{fff}

The Contractor formulated the justification of the selection of each standard on the merits of its intended contribution to a specified hazard control function. For each selected standard or requirement, the Contractor should have described the intended purpose of the selected standard and why it fulfills that purpose. The reviewers should consider the degree to which the Contractor's justification of its standards is consistent with achieving the selected control strategy in a reliable manner based on specified technical objectives. The reviewers should also consider any special circumstances, such as environmental conditions related to various operation modes, off-normal states, or accidents, associated with the achievement of the specified technical objectives that could influence the selection of adequate standards. The reviewers should refrain from advocating personally preferred standards and objectively evaluate the technical adequacy of the Contractor's selected standards to fulfill the specified technical objectives.

Attribute 3 - Use of Precedents^{ggg}

The Contractor selected standards that represent recognized precedents for adequately fulfilling the purposes intended (e.g., endorsed by DOE or NRC, nationally recognized and endorsed, proven by internal use, etc.). The reviewers should consider the degree to which adequate evidence is presented that justifies the use of the precedent standards for achieving the specified technical objectives under the circumstances associated with the Contractor's waste processing facility.

Attribute 4 - Basis for Ad Hoc Standards^{hhh}

The Contractor provided the rationale for developing ad hoc standards and the basis for the Contractor's expectation that these standards will provide the intended function when properly implemented. The reviewers should consider the degree to which adequate evidence is presented that justifies the use of the ad hoc standards for achieving the specified technical objectives under the circumstances associated with the Contractor's waste processing approach. In particular, the reviewers should consider the adequacy of measures cited by the Contractor to compensate for the lack of a body of experience and acceptance normally associated with precedent standards.

Attribute 5 - Graded Approachⁱⁱⁱ

As part of its rationale and justification of the selected standards, the Contractor indicated how its application of a graded approach influenced the resulting selection and why such an application is appropriate for the control of the associated hazard.

Attribute 6 - Balanced Approachⁱⁱⁱ

As part of its rationale and justification of the selected standards, the Contractor indicated how its application of a balanced approach influenced the resulting selection and why such an application is appropriate for the control of the associated hazards (e.g., radiological vs. toxic).

8.5 Integration

As described in the introduction to Section 8, the evaluation of the adequacy of selected standards for control of hazards is an integrated technical review. As a result of the technical reviews performed on a hazard-by-hazard basis using the review guidance of Sections 8.1 through 8.4, evaluation statements of the type described in Section 8 should be available for integration to formulate evaluation statements for each process element and then for the Contractor's waste processing facility. The conclusions for all the hazards and associated hazard events for a process element should be tabulated in a summary form as shown in Exhibit 8-1. This provides a general view of the conclusions and associated patterns.

Based on the integration of inadequacies at the process-element level, overall conclusions should be formulated and documented. Overall conclusions are to be consistent with those identified inadequacies at the process element level and remain valid in the overall context.

Required actions to correct inadequacies are to be compiled and documented. The reviewers should consider the following in performing this evaluation:

- Relationship to lack of maturity of the design.
- Relationship between specific hazards, the means of control, and standards.
- Relationship to an oversight in hazards identification or characterization.
- Relationship to specificity and degree of reliance on the "if properly implemented" clause.
- Relationship to addressing top-level safety standards and principles.
- Relationship to addressing applicable laws and regulations.

An evaluation of required actions to correct inadequacies in the Contractor's proposed control of hazards should be performed. The evaluation should consider:

- Implementation.
- Schedule.
- Practicality.

- Verification.

Exhibit 8-1. Aggregation of integrated technical review conclusions for a process element.

PROCESS ELEMENT _____

A Designates a conclusion of adequacy I designates a conclusion of inadequacy

HAZARD EVENT	ADEQ PROC DESC	ADEQ HAZ ASSESS	AQEQ HAZ CON STRAT	ADEQ HAZ CON STDS	ADEQ SUM	INADEQUACIES	CORRECTIVE ACTIONS

9. Review of Conformance to Top-level Safety Standards and Principles

In accordance with the SRD Approval Criteria, the Contractor's set of standards must conform to the top-level safety standards and principles. Conformance is judgment-based standards application and implementation that demonstrates:

- The standards and principles (and safety objectives) have been addressed and dispositioned.
- Individual standards and principles have been adopted.
- Justifications regarding the implementation of individual standards and principles are documented and based upon considerations of the work, associated hazards, and appropriate control of the hazards.

SRD Approval Criteria

The standards documented in the SRD conform to the top-level radiological, nuclear, and process standards and principles contained in the DOE-provided document titled *Top-Level Radiological, Nuclear, and Process (Safety) Standards and Principles for TWRS Privatization Contractors*, DOE/RL-96-0006, Revision 0.

9.1 Review of Radiological and Nuclear Safety Standards

This portion of the review is focused on the set of standards selected by the Contractor to address exposure limits and radiological releases.

Table 9.1 should be used as the basis for this review; however, it is not a complete set of radiological standards. The reviewers should evaluate the Contractor's selected standards for completeness, including prescribed limits for specific organs and pathways. Consideration should also be given to the Contractor's incorporation of data in Table 1 into its dose standards. The Contractor's limits should equal or be lower than those of Table 9-1. Particular care should be given to the review of the Contractor's dose standards for worker and co-located workers for unlikely and extremely unlikely events.

The Contractor's definitions for boundaries should be compatible with the definitions of Worker, Co-located Worker, and Public. These definitions should be consistent with the areas over which the Contractor and DOE will have lasting (not necessarily permanent) population control. Where the Contractor relies on the services of DOE or another contractor for population control, there should be evidence of the commitment to provide such services by the second party such as a binding contractual agreement.

For radiological standards not included in the *Top-Level Safety Standards and Principles*, the reviewers should evaluate the Contractor's use of accepted national or international standards and the basis for that selection. The Contractor's selected radiological standards should be evaluated for all release pathways to the environment, including air, liquid, and solid forms; airborne concentration; and soil contamination for uncontrolled areas. For items discharged from the facility, the Contractor's selected standards should specify requirements for release of uncontrolled items and transportation packages. Finally, the Contractor's selected standards should be reviewed for emergency response and management and consideration should be given to precedents such as accepted Hanford Site practices.

Table 9-1. Dose Standards Above Normal Background

Description	Estimated Probability of Occurrence $P(\text{yr}^{-1})$	General Guidelines	Worker	Co-located Worker	Public
<u>Normal Events:</u> Events that occur regularly in the course of facility operation (e.g., normal facility operations).	$P \leq 1$	Normal modes of operating facility systems should provide adequate protection of health and safety.	$\leq 5 \text{ rem/yr}^2$ $\leq 50 \text{ rem/yr}$ any organ, skin, or extremity ² $\leq 15 \text{ rem/yr}$ lens of eye ² $\leq 1.0 \text{ rem/yr}$ ALARA design limit ³	$\leq 5 \text{ rem/yr}^3$ $\leq 1.0 \text{ rem/yr}$ ALARA design limit ³	$\leq 10 \text{ mrem/yr}$ (airborne pathway) ⁴ $\leq 100 \text{ mrem/yr}$ (all sources) ⁵ $\leq 100 \text{ mrem/yr}^6$ $\leq 25 \text{ mrem/yr}^7$
<u>Anticipated Events:</u> Events of moderate frequency that may occur once or more during the life of a facility (e.g., minor incidents and upsets).	$10^{-2} < P \leq 1$	The facility should be capable of returning to operation without extensive corrective action or repair.	$\leq 5 \text{ rem/event}^8$ $\leq 1.0 \text{ rem/event}$ ALARA design limit ³	$\leq 5 \text{ rem/event}^8$ $\leq 1.0 \text{ rem/event}$ ALARA design limit ³	$\leq 100 \text{ mrem/event}^8$
<u>Unlikely Events:</u> Events that are not expected, but may occur during the lifetime of a facility (e.g., more severe incidents).	$10^{-4} < P \leq 10^{-2}$	The facility should be capable of returning to operation following potentially extensive corrective action or repair, as necessary.	To be derived ⁹	To be derived ⁹	$\leq 5 \text{ rem/event}^{10}$

Table 9-1. Dose Standards Above Normal Background (continued)

Description	Estimated Probability of Occurrence P(yr ⁻¹)	General Guidelines	Worker	Co-located Worker	Public
<u>Extremely Unlikely Events</u> ¹¹ . Events that are not expected to occur during the life of the facility but are postulated because their consequences would include the potential for the release of significant amounts of radioactive material.	$10^{-6} < P \leq 10^{-4}$	Facility damage may preclude returning to operation.	To be derived ⁹	To be derived ⁹	≤ 25 rem/event ¹² ≤ 300 rem/event to thyroid ¹²

Table Notes

- ¹ Dose is assumed to be the committed effective dose equivalent from inhaled radionuclides and any direct radiation from the accident
- ² 10 CFR 835.202 Occupational exposure limits for general employees and 10 CFR 20.1201 Occupational dose limits for adults
- ³ 10 CFR 835.1002(b) Facility design and modification
- ⁴ Proposed Rule 10 CFR 834.102(2) Airborne emissions only, all DOE sources of radionuclides (60 FR 47498, Federal Register, 9/13/95) and 40 CFR 61.92 Public dose from emissions of radionuclides to the ambient air from DOE facilities
- ⁵ Proposed Rule 10 CFR 834.101 Public primary dose limit (60 FR 47498, Federal Register, 9/13/95) and 10 CFR 20.1301(a)(1) Dose limits for individual members of the public
- ⁶ 10 CFR 835.206 Limits of members of the public entering a controlled area and 10 CFR 20.1301(b) Dose limits for individual members of the public
- ⁷ Proposed Rule 10 CFR 834.221 Public primary dose limit for radioactive waste (60 FR 47498, Federal Register, 9/13/95)
- ⁸ Proposed Rule 10 CFR 60 Disposal of high-level radioactive waste in geologic repositories; design basis events (60 FR 15180, Federal Register, 3/22/95)
- ⁹ Specific limits to be derived and proposed by the Contractor. Examples of such derived limits and implementation approaches are described in the DOE/EH report *Methods for the Assessment of Worker Safety Under Radiological Accident Conditions at Department of Energy Nuclear Facilities*, EH-12-94-01, June 1994. Specific limits will be finalized as part of the standards

identification and approval activities to be performed early in Part A of the program.

- ¹⁰ 10 CFR 72.106 Control area of an independent spent fuel storage installation or monitored retrievable storage facility
- ¹¹ They represent the upper bounds on failures or accidents with the probability of occurrence sufficiently high to require consideration in the design.
- ¹² 10 CFR 100.10 Siting evaluation factors.

9.2 Review of Radiological and Nuclear Safety Objectives⁵⁸

The General Safety Objectives⁵⁹ as stated in the *Top-level Standards and Principles*, establish an envelope of acceptable radiation exposure risks that the Contractor must incorporate as part of the standard selection process. These objectives include the Operations Risk Goal, Accident Risk Goal, and Worker Accident Risk Goal.

Operations Risk Goal

The risk, to the population (public and workers) in the area of the Contractor's facility, of cancer fatalities that might result from facility operation should not exceed one-tenth of one percent (0.1%) of the sum of cancer fatality risks to which members of the U.S. population generally are exposed. [For evaluation purposes, individuals are assumed to be located within 10 miles of the controlled area.]

Accident Risk Goal

The risk, to an average individual in the vicinity of the Contractor's facility, of prompt fatalities that might result from an accident should not exceed one-tenth of one percent (0.1%) of the sum of prompt fatality risks resulting from other accidents to which members of the U.S. population generally are exposed. [For evaluation purposes, individuals are assumed to be located within one mile of the controlled area.]

Worker Accident Risk Goal

The risk, to workers in the vicinity of the Contractor's facility, of fatality from radiological exposure that might result from an accident should not be a significant contributor to the overall occupational risk of fatality to workers. [For evaluation purposes, workers are assumed to be located within the controlled area.]⁶⁰

The Radiation Protection Objective requires the Contractor to ensure that all radiation exposures within the facility and exposures and environmental impacts due to any release of radioactive material during normal facility operations are kept as low as reasonably achievable (ALARA) and within prescribed limits. This objective also requires the Contractor to ensure

⁵⁸ *Top-Level Safety Standards and Principles*, Section 3, pp. 4-5.

⁵⁹ *Ibid*, Section 3.1.

⁶⁰ *Ibid*, Section 3.2.

mitigation of the extent of radiological exposures and environmental impacts due to accident conditions. The Reviewer should ensure that the Contractor's selected standards address the minimum prescribed limits and in no way inhibit the implementation of an aggressive ALARA program.

The Technical Safety Objectives⁶¹ requires the Contractor to ensure that measures in the design and operations of the facility to protect the public and the worker against accident conditions are evaluated by the Contractor against acceptable guidelines contained in the selected set of standards. The Contractor's evaluation must demonstrate that the design and operational measures perform with a high level of confidence. Additionally, the set of selected standards should allow the incorporation of a process to identify, evaluate and prevent and/or mitigate any reasonable vulnerability to an accident. The Reviewer should verify that the Technical Safety Objectives are achievable within the framework of the Contractor's selected set of standards.

9.3 Review of General Radiological and Nuclear Safety Principles

The General Radiological and Nuclear Safety Principles,⁶² are fundamental ways to achieve safety through proven radiological and nuclear practices. These practices are to be incorporated into the Contractor's facility design and operations. The Contractor's set of selected standards should; therefore, be compatible with these safety principles. The Reviewer should evaluate the Contractor's standards and verify that the selected standards allow implementation of these safety principles.

Overall Principles⁶³ are broad in scope and encompass concepts that effect every aspect of facility design, operation, maintenance, and deactivation. These principles include the following: Defense in Depth, Safety Responsibility, Authorization Basis, Safety/Quality Culture, Configuration Management, and Quality Assurance. The reviewers should determine the compatibility of the standards with these principles.

The principles listed in Design, Construction, and Pre-Operational Testing⁶⁴ are tied directly to the design of the Contractor's facility. These principles include the following: Design; Proven Engineering Practices/Margins; Radiation Protection; Emergency Preparedness; Inherent/Passive Safety Characteristics; Human Factors; and Reliability, Availability, Maintainability, and Inspectability (RAM); Pre-Operational Testing. The reviewers should ensure that these principles are part of the Contractor's design process and that the all selected standards used in the design are compatible with utilization of the stated principles.

Likewise, the principles listed in Operation⁶⁵ are tied directly to the operations of the Contractor's facility. These principles include the following: Conduct of Operations; Radiation Protection; Emergency Preparedness; Training and Qualification; Operational Testing,

⁶¹ *Top-Level Safety Standards and Principles*, Section 3.3.

⁶² *Ibid*, Section 4, pp. 6-14.

⁶³ *Ibid*, Section 4.1, pp. 6-8.

⁶⁴ *Ibid*, Section 4.2, pp. 8-11.

⁶⁵ *Ibid*, Section 4.3, pp. 11-13.

Inspection and Maintenance; and Security. The reviewers should ensure that these principles are part of the Contractor's facility operational plans and that the all selected standards which will be used to develop the operations of the facility are compatible with implementation of the stated principles.

Internal Safety Oversight⁶⁶ calls for the establishment and implementation of the Contractor's internal safety program. Important elements of this program are stated in the following principles: Safety Review Organization, Qualified Personnel, Recommendation for Initiation of Construction, and Unresolved Safety Questions (USQ). The reviewers should ensure that the Contractor's selected set of standards allow for the organization and implementation of an internal safety program.

9.4 General Process Safety Principles⁶⁷

The General Process Safety Principles are fundamental ways to achieve process safety through proven industry practices. These practices shall be addressed in the Contractor's set of selected standards. The Reviewer should evaluate the Contractor's standards and verify that the selected standards allow implementation of these safety principles.

The Overall Principles⁶⁸ are broad-based concepts that reflect the need for the Contractor to implement a comprehensive process safety management program. The principles also state that the Contractor has the ultimate responsibility for process safety. The reviewers should determine the compatibility of the standards with these principles.

Process Safety Management Program⁶⁹ briefly states elements which need to be considered by the Contractor to adequately implement the process safety management program. The Contractor set of selected standards should contain and/or be compatible with the elements described in this program.

10. Review of Compliance to Laws and Regulations

This section of the review determines if the Contractor has identified and included all applicable laws and regulations in the SRD. The SRD must include the rationale for the selection of standards, identify the complete standards set, explain the process for approving the standards and show how the standards are certified. Within this framework, the SRD must assure compliance with applicable laws and regulations.

Related Submittal Requirements

The Contractor's Standards Approval documentation shall include a certification that the set of radiological, nuclear, and process standards in the SRD will, when implemented, provide adequate safety, comply with all applicable laws and regulations, and conform to the DOE-

⁶⁶ *Ibid*, Section 4.4, p. 14.

⁶⁷ *Top-Level Safety Standards and Principles*, Section 5, p. 15.

⁶⁸ *Ibid*, Section 5.1.

⁶⁹ *Ibid*, Section 5.2.

stipulated top-level safety standards and principles.⁷⁰

Approval Criterion

The approval of the Contractor's recommended set of radiological, nuclear, and process safety standards and requirements will be issued upon determination by the Director of the Regulatory Unit that the set documented in the SRD includes all requirements of applicable laws and regulations.⁷¹

Review

The reviewers should verify that the set of laws identified is consistent with comparable waste treatment facilities (i.e., DWPF, West Valley). In reviewing State Laws, the reviewers may wish to examine the records for local facilities at the Hanford Site that bear similarities to TWRS Privatization (e.g., the Canister Storage Facility). Laws and regulations to be considered include 10 CFR 830.120, 10 CFR 835, and other proposed 10 CFR 830 Regulations.⁷²

Attribute 1 - Adequacy of Standards Set^{kkk}

The Contractor provided its basis for determining that the selected set of standards in the SRD, when properly implemented, will comply with all applicable laws and regulations and provided the information necessary to demonstrate that this basis has been satisfied by the selected set.

Review Considerations

The reviewers should evaluate the standards identification process that is related to compliance with the Law. Consideration should be given to whether a thorough review of the law was conducted, or whether the Contractor merely restated the obvious list of laws cited above. The reviewers should consider the details of the laws with respect to the standards of the SRD. If aspects of the law are identified that are not committed to in the SRD, notations should be made. The reviewers should note if the Contractor reports the basis for its determination is that the set of standards complies with all laws. If the basis for compliance is not clearly described in the SRD, this should also be documented.

Attribute 2 - Linkage to Laws and Regulations^{lll}

The Contractor designated in its presentation of the selected standards in the SRD those standards that directly support compliance to applicable laws and regulations. This designation can be made at the discretion of the Contractor as long as it is clear and complete, and the association with the particular applicable laws and regulations can be easily followed.

Attribute 3 - Assurance of Adequacy Compliance to Applicable Laws and Regulations^{mmm}

⁷⁰ *Regulatory Process*, Section 4.1.2, item 2, p. 11.

⁷¹ *Ibid*, Section 3.3.1, item 1, p. 4.

⁷² 60 FR 47498, *Federal Register*, September 13, 1995.

The Contractor's approval addressed the adequacy of the standards set in terms of providing adequate compliance to the applicable laws and regulations.

Review Considerations

Consideration should be given to the formal approval process with respect to the adequacy of the standards set for legal compliance. In this process, the ESH Standards Expert is responsible for identifying any legal requirements that do not add value. The reviewers should consider whether the Contractor intends to apply for an exemption to a given law or regulation. In addition, the reviewers should consider whether the Confirmation of Standards by the IRT included consideration of compliance to the law.

Attribute 4 - Contractual Agreementⁿⁿⁿ

The Contractor provided a written certification that states that the set of radiological, nuclear, and process standards in the SRD will, when implemented, comply with all applicable laws and regulations. This certification constitutes a contractual commitment by the Contractor in partial fulfillment of the terms of its current TWRS Privatization Contract with DOE. The certification and recognition of the more defined contractual commitment is in a notarized letter from the Contractor.

Review Considerations

With regard to compliance to law, the Signatory has the legal authority to act on behalf of the Contractor Corporation. The reviewers should consult with legal experts.

Findings

The reviewers should integrate the detailed considerations outlined above into a recommendation to the RU that, with regard to compliance with the law, the Contractor's standards set should either be:

- Approved - The SER should document the basis for this overall finding, referring to the detailed findings documented in the SER
- Disapproved - The SER should provide the rationale for the rejection decision. In this instance, very detailed documentation of the basis for the rejection is required, including a discussion of the decision making process used. Note that in this review area, failure to show compliance with a single law is tantamount to rejection. Legal opinions should be documented in a formal legal manner and reviewed by the DOE/RL Office of General Counsel.

11. Review of Standards Set Justification

This portion of the review is to evaluate the Contractor's justification for the set of standards selected. The review conducted in this section should support the overall RU evaluation of the whether the SRD should be approved or disapproved.

In making an integrated evaluation of the SRD, the summary results of the evaluations performed in Section 9 (conformance to top-level standards) and Section 10 (compliance with law) and should be brought forward into the reviewers evaluation of the justification of standards in this section. In addition, Table 5-1 shows that the evaluation of "adequate safety"

comprises a combined review of the hazards control (Section 8) and the standards set justification (this section). In general, the review must be thoroughly documented, especially when integration of the overall results is performed.

Approval Criterion

The set documented in the SRD will provide adequate safety if properly implemented.⁷³

11.1 Standards Set Justification

Related Submittal Requirement

The Contractor's Standards Approval documentation shall include the rationale for the selection of the standards and the adequacy of the set.⁷⁴

Contract Considerations

This concept of the Contractor's role in the identification of safety standards and requirements that apply to its activities is consistent with Criteria for the Department's Standards Program (DOE/EH/-0416, 1994). DOE's Standards Program includes the essential function that justification⁷⁵ of the adequacy of the applicable standards.

Policy Consideration

Standards Identification - A DOE-defined process shall be established and stipulated to the contractor for the contractor's preparation of a set of subordinate safety standards and requirements. This process shall, as a minimum, demonstrate compliance with applicable laws and regulations. Standards not relied upon for justification of the adequacy of the set need not be dispositioned.⁷⁶

Approval Considerations

The complete list of approval considerations is repeated here in reference to making the final SRD approval/disapproval decision. These considerations also bear on the reviewers' evaluation of the adequacy of the standards set.

The approval of the Contractor's recommended set of radiological, nuclear, and process safety standards and requirements will be issued upon determination by the Director of the Regulatory Unit [the Regulatory Official] that:

⁷³ *Regulatory Process*, Section 3.3.1, bullet 6, p. 5.

⁷⁴ *Ibid*, Section 4.1.2, Part 7.

⁷⁵ *Standards Identification Process*, Section 2, p. 2.

⁷⁶ *Policy for Radiological, Nuclear and Process Safety Regulation of TWRS Privatization Contractors*, DOE/RL-96-25, July 3, 1996, p. 5.

- 1) The set documented in the SRD includes all requirements of applicable laws and regulations;
- 2) The set documented in the SRD conforms to the top-level radiological, nuclear, and process standards and principles contained in the DOE-provided document titled Top-Level Radiological, Nuclear, and Process Standards and Principles for TWRS Privatization Contractors, DOE/RL-96-0006, Revision 0;
- 3) The hazards associated with the proposed facility and its operation are appropriately assessed;
- 4) The set documented in the SRD was generated through the appropriate implementation of the standards process stipulated by DOE in the document titled Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization, DOE/RL-96-0004, Revision 0;
- 5) Appropriate expertise was employed in the standards selection and confirmation processes; and
- 6) The set documented in the SRD will provide adequate safety if properly implemented.

Intent of Requirement

The standards in the SRD are subject to changes in the process and facility design; hazards, rules, regulations, and requirements; and contractual conditions. The rationale and justification for the selected standards serves as a basis for determining the need to modify the SRD. In addition this information supports the RU evaluation of adequacy of the SRD.

Review

The reviewers should consider the following attributes in their review.

Attribute 1 - Justification Scope^{ooo}

The Contractor documented and provided justifications for those standards selected. There is no expectation that the Contractor submit documentation that justifies the reasons all other standards were not selected.^{ppp} Appropriate linkage between each selected standard or requirement to its role in the control of hazards or satisfaction of rules, regulations, and contract requirements^{qqq} should be provided.

Attribute 2 - Justification Basis^{rrr}

The Contractor formulated the justification of the selection of each standard or requirement on the merits of its intended contribution to a specified hazard control function or satisfaction of rules, regulations, and contract requirements. For each selected standard or requirement, the reviewers should consider whether the Contractor described the intended purpose of the selected standard or requirement and why it fulfills that purpose.

Attribute 3 - Use of Precedents^{sss}

The Contractor selected standards that represent recognized precedents for adequately fulfilling the purposes intended (e.g., endorsed by DOE or NRC, nationally recognized and endorsed, proven by internal use, etc.).

Attribute 4 - Basis for Ad Hoc Standards^{ttt}

The Contractor provided the rationale for developing ad hoc standards and the basis for their expectation that these standards will provide the intended function when properly implemented.

Attribute 5 - Graded Approach^{uuu}

The reviewers should consider how the Contractor applied a graded approach in their standards selection and why such an application is appropriate for the control of the associated hazard or satisfaction of rules, regulations, and contract requirements.

Attribute 6 - Trade-offs^{vvv}

The reviewers should consider how the Contractor's application of trade-offs influenced the resulting selection and why such an application is appropriate for the control of the associated hazards (e.g., radiological, toxic, explosive, etc.).

Attribute 7 - Adequacy of Standards Set^{www}

The reviewers should evaluate the Contractor's basis for determining that the selected set of standards, when properly implemented, provide adequate safety, comply with applicable laws and regulations, and conform to the DOE stipulated top-level safety standards and principles; and evaluate whether the Contractor provided the information necessary to demonstrate that this basis has been satisfied by the selected set.

11.2 SRD Approval or Disapproval

The Review team shall recommend either approval or disapproval of the SRD to the Regulatory Official. The final recommendation should be a consensus amongst the Review Team. The key review requirement is that the basis for the final recommendation to the Regulatory Official (RO) be clearly articulated and defensible as presented in the SER.^{xxx}

a. Approval

To recommend approval of the SRD to the Regulatory Official, the reviewers must conclude that the Contractor has met all of the approval criteria. The process by which technical differences of opinion are resolved among the reviewers is described in the Review Team charter. The assessment of the Review Team will be thoroughly documented, including the method used to come to the approval determination and the elements considered in reaching the decision. The Review Team may recommend approval contingent upon the submittal of additional information from the Contractor by a specified date.

In some cases, especially in the area of risk-informed decision making, the Contractor's may define the relationship between the standards selected and the relative risks associated with

hazards when the ISA is completed and/or when work on the SAR is under way during Part B. This may be acceptable, since what is implied is tailoring of the standards using a graded approach to safety.

b. Disapproval

To recommend disapproval of the SRD to the Regulatory Official, the Review Team must conclude that the Contractor has failed to meet one or more of the approval criteria. The RU will provide the Contractor with a clear, written explanation of the areas of the SRD submittal which failed to meet the approval criteria.

12. Abbreviations

ALARA As Low as Reasonable Achievable

CFR Code of Federal Regulation

CM Configuration Management

CR Contractor Representative

CR Contractor Representative

DC DOE Customer

DOE Department of Energy

ESE ESH Standards Experts

FSAR Final Safety Analysis Report

HAE Hazards Assessment Experts

HAE Hazards Assessment Experts

HCE Hazards Control Experts

ISA Initial Safety Assessment

IRT Independent Review Team

NRC Nuclear Regulatory Commission

PM Process Manager

PMT Process Management Team

PSAR Preliminary Safety Analysis Report

RFP TWRS Privatization Request for Proposal

RL Richland Operations Office

RMRU Review Manager from Regulatory Unit

RU Office of Radiological, Nuclear, and Process Safety Regulation (Regulatory Unit)

SAP Standards Approval Package

SAR Safety Analysis Report

SRD Safety Requirements Document

SSC Structures, Systems, and Components

TWRS Hanford Tank Waste Remediation System

USQ Unresolved Safety Questions

WAE Work Activity Experts

13. Glossary^{yyy}

Administrative Controls. Provisions relating to organization and management, procedures, record keeping, assessment, and reporting necessary to ensure safe operation of a facility.

Attribute. This Guide uses “attributes” as review considerations for evaluating the Contractor’s submittal against specific requirements. The attributes describe considerations which the reviewers may use to reach conclusions about the acceptability of the submittal. The attributes listed may not be exhaustive. The reviewers may invoke other considerations in the review in accordance with the Reviewer’s experience and expertise.

Design.^{zzz} The process and the result of developing the concept, detailed plans, supporting calculations and specifications for a nuclear facility and its parts.

Document. Document means recorded information that describes, specifies, reports, certifies, requires, or provides data or results. A document is not considered a record until it meets the definition of record.

Graded Approach. A process by which the level of analysis, documentation, and actions necessary to comply with a requirement in this part are commensurate with:

- 1) The relative importance to safety, safeguards, and security;
- 2) The magnitude of any hazard involved;
- 3) The life cycle stage of a facility;
- 4) The programmatic mission of a facility;
- 5) The particular characteristics of a facility; and
- 6) Any other relevant factor.

Hazard Assessment. As used in this Review Guide, Hazard Assessment comprises the

approach outlined^{aaaa} in DOE Standard 3009-94.

Hazard Evaluation. The analysis of the significance of hazardous situations associated with a process or activity. Uses qualitative techniques to pinpoint inadequacies in the design and operation of facilities that could lead to accidents.^{bbbb} Hazard Evaluation techniques include HAZOP Analysis, Fault, and Event tree analysis and other methods.

Initial Safety Assessment (ISA). The Initial Safety Assessment (ISA) will be submitted by the Contractor at the end of Part A. A somewhat detailed definition of the ISA is included in this glossary to remind the reviewers of some of the distinctions between information anticipated in the SRD and that in the ISA. Among other things, this shall consist of the following documentation:

- 1) Description of the design developed during Part A and the proposed facility operations;
- 2) Description of the Contractor's site and its location within the Hanford Site;
- 3) An assessment of compliance to the approved SRD and the ISMP;
- 4) Description of hazards, including process hazards, and hazards controls implemented in the design and operations;
- 5) Description of potential design-basis events;
- 6) Analysis of the potential design-basis events;
- 7) Preliminary safety acceptance criteria against which the consequences of the potential design-basis events are compared for acceptability;
- 8) Description of structures, systems, and components designated as important to safety and the rationale for their selection;
- 9) The Contractor's evaluations of constructability, operability, reliability, availability, maintainability, and inspectability;
- 10) An Initial Safety Analysis Report that Defines the projected safety basis for the facility (safety envelope) in terms of physical design, structures with prescribed safety functions, systems with prescribed safety functions, equipment with prescribed safety functions, operating modes, operating conditions, representative off-normal internal events, representative external events, representative safety analyses and results, major uncertainties in data and analyses.⁷⁷

Item. Item is an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, or support systems.

Nonreactor Nuclear Facility. Those activities or operations that involve radioactive and/or

⁷⁷ *Regulatory Process*, p. 14.

fissionable materials in such form and quantity that a nuclear hazard potentially exists to the employees or the general public. Incidental use and generating of radioactive materials in a facility operation (e.g., check and calibration sources, use of radioactive sources in research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines) would not ordinarily require the facility to be included in this definition. Transportation of radioactive materials, accelerators and reactors and their operations are not included. The application of any rule to a nonreactor nuclear facility shall be applied using a graded approach. Included are activities or operations that:

- 1) Produce, process, or store radioactive liquid or solid waste, fissionable materials, or tritium;
- 2) Conduct separations operations;
- 3) Conduct irradiated materials inspection, fuel fabrication, decontamination, or recovery operations;
- 4) Conduct fuel enrichment operations;
- 5) Perform environmental remediation or waste management activities involving radioactive materials; or
- 6) Design, manufacture, or assemble items for use with radioactive materials and/or fissionable materials in such form or quantity that a nuclear hazard potentially exists.

Nuclear Facility. Reactor and nonreactor nuclear facilities.

Process. (Related to Quality Assurance) A series of actions that achieves an end or result.

Process Element. A component, subsystem, system, or region within of the facility. Each Contractor may define different process elements when performing their hazards evaluations.

Quality. The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

Quality Assurance. All those actions that provide confidence that quality is achieved.

Quality Assurance Program or QAP. The overall program established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

Record. A completed document or other media that provides objective evidence of an item, service, or process.

Regulatory Official. Director of the Regulatory Unit.

Regulatory Unit. The organization reporting to the Director of the Regulatory Unit dedicated to supporting the Director in executing regulatory authority.

Related Submittal Requirement.

Service. The performance of work, such as design, construction, fabrication, inspection,

nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

SRD Submittal Package. The Contractor's submittal documentation for the SRD, which contains:

- 1) The Contractor's recommended set of radiological, nuclear, and process standards for design, construction, operation, deactivation, and regulatory submittals in the form of a SRD;
- 2) The Contractor's certification that the set of radiological, nuclear, and process standards in the SRD will, when implemented, will provide adequate safety, comply with all applicable laws and regulations, and conform to the DOE-stipulated top-level safety standards and principles;
- 3) The hazards assessment used to facilitate the selection of the standards;
- 4) The hazards control strategy implemented in the design and proposed operations;
- 5) Description of the process and facility design and its proposed operation;
- 6) The Contractor's treatment of the top-level radiological, nuclear, and process safety standards and principles;
- 7) The rationale for the selection of the standards and the adequacy of the set;
- 8) The standards identification process used and the credentials of the participants;
- 9) The standards confirmation process used and the credentials of the participants;
- 10) The Contractor's approval process used for the set of standards and the basis for the approval.⁷⁸

Standards Approval Package. The combined SRD and the ISMPs.

Submittal Requirement. Information required of the Contractors under the authority of the TWRS Privatization Contracts, and the four documents incorporated in the Contracts.

⁷⁸ *Regulatory Process*, p. 14.

ENDNOTES

Endnotes, unless otherwise noted, are taken from sections of the *Discussion Paper for DOE/RU Review of the Safety Requirements Document and the Integrated Safety Management Plan Submitted by the TWRS Privatization Contractor*, RL/REG-97-02, Revision 0, March 27, 1997.

- a. Section 5.4.3.2.
- b. Section 5.4.3.1.
- c. This is an additional attribute. It is not included in the *Discussion Paper*.
- d. Section 5.4.3.3.
- e. Section 5.4.3.4.
- f. Section 5.4.3.5.
- g. Section 5.4.3.6.
- h. Section 5.4.3.7.
- i. Section 5.4.3.8.
- j. Section 5.4.3.9.
- k. *Ibid.*
- l. Section 5.2.3.1.
- m. Section 5.2.3.3.
- n. Section 5.2.3.6.
- o. Section 5.3.3.1.
- p. Section 5.3.3.2.
- q. Section 5.3.3.6.
- r. Section 5.5.3.1.
- s. Section 5.5.3.2.
- t. Section 5.6.3.1.
- u. From Table 1, *Standards Identification Process*, p. 4.
- v. Section 5.6.3.4.
- w. Section 5.6.3.5.

x. Section 5.6.3.7.

y. Section 5.6.3.8.

z. Section 5.9.3.1.

aa. Section 5.9.3.2.

bb. Section 5.9.3.3.

cc. Section 5.9.3.4.

dd. Section 5.9.3.5.

ee. Section 5.9.3.6.

ff. Section 5.10.3.1.

gg. Section 5.10.3.2.

hh. Section 5.1.3.1.

ii. Section 5.1.3.2.

jj. Section 5.1.3.3.

kk. Section 5.1.3.4.

ll. Section 5.1.3.5.

mm. Section 5.1.3.6.

nn. Section 5.1.3.7.

oo. Section 5.2.3.1.

pp. Section 5.2.3.2.

qq. Section 5.2.3.3.

rr. Section 5.2.3.4.

ss. Section 5.2.3.5.

tt. Section 5.2.3.6.

uu. *Final Safety Analysis Report Savannah River Site Defense Waste Processing Facility*, WSRC-SA-6, Chapter 9, November 1995; TWRS Draft Safety Analysis Report; WVDP Safety Analysis Report; and D. R. MacFarlane, et. al., “*Probabilistic Safety Assessment for Hanford High-Level Waste Tanks*”, Los Alamos National Laboratory report, November 1995.

vv. Section 5.2.3.7.

ww. Section 5.3.3.1.

xx. *Final Safety Analysis Report Savannah River Site Defense Waste Processing Facility*, WSRC-SA-6, Chapter 9, November 1995; WVDP Safety Analysis Report; British source of hazards control information; and French source of hazards control information.

yy. Section 5.3.3.2.

zz. DOE Standard 3009.

aaa. Section 5.3.3.3.

bbb. Section 5.3.3.4.

ccc. Section 5.3.3.5.

ddd. Section 5.3.3.6.

eee. Section 5.5.3.1.

fff. Section 5.5.3.2.

ggg. Section 5.5.3.3.

hhh. Section 5.5.3.4.

iii. Section 5.5.3.5.

jjj. Section 5.5.3.6.

kkk. Section 5.5.3.7.

lll. Section 5.7.3.2.

mmm. Section 5.9.3.5.

nnn. Section 5.10.3.1.

ooo. Section 5.5.3.1.

ppp. However, in anticipation of future internal standards activities involving participants not familiar with the evolution of the standards set, the Contractor may benefit from retaining records documenting decisions to deliberately exclude standards that may, on the surface, appear applicable.

qqq. Mandates include rules, regulations, and contract mandated requirements.

rrr. Section 5.5.3.2.

sss. Section 5.5.3.3.

ttt. Section 5.5.3.4.

uuu. Section 5.5.3.5.

vvv. Section 5.5.3.6.

www. Section 5.5.3.7.

xxx. It should be anticipated that the SER will be carefully reviewed by the DNFSB, DOE Headquarters personnel (especially under the independent review provision for EH), the NRC, the Contractor, and the public. The review findings must be solidly based and defensible amongst all such groups.

yyy. Definitions from the DOE/RL-0003 through -0006 documents are not repeated in this Glossary.

zzz. Derived from the definition of design used in IAEA Code on the Safety of Nuclear Power Plants: Quality Assurance, 50-C-QA (Rev. 1).

aaaa. *Preparation Guide for U.S. Department of Energy Nonreactor Nuclear Facility Safety Analysis Reports*, DOE Standard, DOE-STD-3009-94, July, 1994.

bbbb. *AIChE Guidelines*, p. xxv.